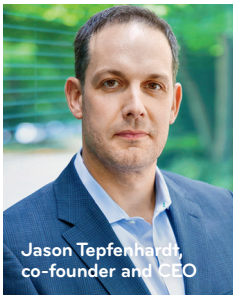
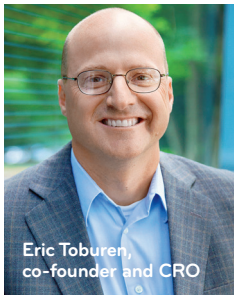
LIFE SCIENCES COMPLIANCE, DRIVEN BY DATA

Automating computer system testing improves efficiency and quality while facilitating digital transformation


Jason Tepfenhardt, co-founder and CEO


Eric Toburen, co-founder and CRO

When it comes to test automation compliance in life sciences, Tx3 Services steps up to the plate with a team of industry experts and an electronic signature solution to put its customers' minds at ease. Tx3, a software and consulting company, "is well positioned to address regulatory compliance challenges with VERA (Validated Electronic Record Approval). VERA supports the use of automation tools to modernize software development and testing practices by securing electronic records through configurable workflow controls and electronic signature approvals," says Jason Tepfenhardt, co-founder and CEO. "We work closely with leading tool providers such as our partner, MicroFocus," he added.

IN PURSUIT OF OPERATIONAL EFFICIENCY

The mission from Tx3's start was making it possible for life sciences companies, comprised of pharmaceutical, biotech, and medical device manufacturers, to automate the testing of computer systems, to make them more efficient and effective. It was essential that they meet U.S. Food and Drug Administration (FDA) requirements, in particular, 21 CFR Part 11. Life science companies need to be able to prove to the FDA that systems impacting human health are designed and function based on their intended use—a process called computer systems validation.

Historically, computer system validation was a paper-based/document-centric process, with data stored in electronic documents or spreadsheets. Companies today still struggle with reducing the amount of paper involved in the manual process. Converting files into pdf format for review and approval offers some improvement. However, having information in a document form (paper or pdf) makes it virtually impossible to leverage the inherent value of the data, explains Eric Toburen, co-founder and CRO. Shifting to a data-driven process provides the ability to analyze data and create dashboards with real-time insights into the process.

Clients achieve as much as a 70 percent gain in efficiency from implementing VERA to enable the adoption of automation tools, Tepfenhardt says. That high return on investment, coupled with process improvements, result in a 98 percent VERA subscription-renewal rate.

"Our solutions are designed to help keep business-critical resources focused on their areas of expertise. Pharma's mission should be to discover drugs, improve patient outcomes, and improve quality of life through medicine, not to become an IT testing shop," says Tepfenhardt.

HIRING ONLY THE BEST

Many of Tx3's clients rely on the expertise of the firm's skilled staff members to decipher what they need in order to be in compliance. Serving as strategy consultants, in many respects, Tx3 has quickly gained the trust of its growing client base, which relies on the team for advice in improving their processes and deploying critical software quality tools.

That in-house expertise is by design. From the start, Tx3 hired only senior-level professionals with years of experience, helping the firm gain traction quickly.

"A significant contributor to Tx3's success during the last five years has been the unwavering support of our loyal customer base and community of industry peers, who help drive the solutions we provide," says Tepfenhardt. "Our ultimate goal is to ensure that our customers and employees are both successful."

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12
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GLOBAL PHARMA COMPANIES AS CUSTOMERS